LIBELED: 4–27–59, Dist. Minn.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for slenderizing and improving the figure; reshaping the figure for better health; easing sore muscles and joints; eliminating fat deposits in specific areas of the body; and building healthy tissues.

DISPOSITION: 6–30–59. Default—delivered to Food and Drug Administration.

6040. Phonograph records. (F.D.C. No. 42933. S. Nos. 47–833/7 P.)

QUANTITY: 50 sets, each set consisting of a folder of 3 records each, at Windsor, Conn.

SHIPPED: 2–3–59 and 3–19–59, from Chicago, Ill., by Audio-Suggestion Institute, Inc.

LABEL IN PART: (Record) "Audio Suggestion Institute * * * Pressed for Audio Suggestion Institute."

ACCOMPANYING LABELING: Booklet in folder entitled "Applied Home Hypnotherapy"; leaflets entitled "Are You Digging Your Own Grave?"; letterheads entitled "I hereby order and agree" and "Agents/Your Profit Schedule"; sales instructions entitled "Direct Sales Approach"; letterhead applications to become a dealer; reprints of articles from the 10–29–58, 10–28–58, and 2–2–59 issues of the Chicago Daily Tribune; reprints of article from the 8–17–58 issue of the Chicago Sun Times; reprints of article from the December 1958 issue of the Cosmopolitan magazine; reprints of portions of articles from the August 1958 issue of True Story magazine, September 1958 issue of McCall's magazine, and July 1958 issue of Science Digest magazine; reprints of a portion of 11–3–58 issue of Life magazine; reprints of letterhead entitled "Home Hypnotherapy Course/Complete course 202A * * *"; reprints of portion of article from October 1956 issue of Reader's Digest magazine; reprints of testimonial letters dated 7–9–58 by Mrs. Wm. Hutchinson and 7–12–58, by Mrs. Viola Granado; reprints of article from the November issue of Popular Medicine magazine; reprints of letter to "Fred X. Stark, Pres." signed by "George B. Stone" containing ad "Can't Lose Weight?"; reprints of article from the 2–11–59 issue of the Chicago Daily News.

LIBELED: 4–16–59, Dist. Conn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that it was an adequate and effective treatment for improving mental health and well being; causing one to become a dynamic, vigorous personality; providing a healthier, happier, more abundant life; curing mental distress; controlling the appetite; overcoming nervous tension, headaches, insomnia, smoking habit, nail biting, indigestion, overeating, alcoholism, frigidity, impotence, cerebral palsy, bed wetting, asthmatic attacks, menopausal difficulties, paralysis of polio, tuberculosis, arthritis, sinus trouble, blindness, cancer, neurosis, ulcers, stammering, skin troubles, bad habits, and anxieties; healing wounds; curing warts; reducing or gaining weight; increasing sexual powers; and that the article would provide through "home hypnotherapy" a means of overcoming specific problems.

DISPOSITION: 6–19–59. Default—delivered to the Food and Drug Administration.

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6041–6080

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, when shipped to a holder of a guaranty, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent and (2) criminal proceedings terminated upon pleas of nolo contendere and guilty or by judgments of guilty and not guilty after trial. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *November 18, 1960.*

CONTENTS*

*For violative sale of prescription drugs, see No. 6041; drugs in violation of prescription labeling requirements, Nos. 6041, 6043; omission of, or unsatisfactory, ingredients statements, Nos. 6041, 6043, 6047, 6056; an imitation of, and sale under name of, another drug, No. 6041; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6041, 6043; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6041, 6043; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 6043; cosmetics, actionable under the drug provisions of the Act, Nos. 6048, 6068.

566857—60——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. 6041–6080

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its quality differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its quality fell below that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(c), certain information required by the Act to appear on the label or labeling was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug and (3) the article was offered for sale under the name of another drug; Section 502(l), one article contained penicillin, one article contained chloramphenicol, and one article contained manganese bacitracin, and none of the articles were from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6041. Imitation Miltown tablets and imitation Equanil tablets. (F.D.C. No. 42166. S. No. 27–359 M.)

INDICTMENT FILED: 4–22–59, S. Dist. N.Y., against Seymour Blau, Ludwig Spandau, and Salude Laboratories, Inc., New York, N.Y.

ALLEGED VIOLATION: The indictment alleged that the defendants, with intent to defraud and mislead, caused to be introduced into interstate commerce, quantities of *imitation Miltown tablets* and *imitation Equanil tablets* containing meprobamate, which were new drugs and were adulterated and misbranded.